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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,065	01/22/2008	Jules B. Puschett	205204-00018-1-1	2038

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1628	
MAIL DATE	DELIVERY MODE
08/08/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,065	PUSCHETT, JULES B.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment July 5, 2011 filed have been received and entered into the application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raghunathan (U.S.Patent No. 4,517,179) in view of McCarty (U.S.Patent No. 5,776,504) and further in view of American Hospital Formulary Service Drug Information 88 (AHFS88).

Raghunathan teaches that Applicant's active agent, metolazone is an antihypertensive agent (column 1 lines 24-28).

Raghunathan does not teach the employment of metolazone for the treatment of pre-eclampsia, effective amounts set forth in claims 1, 7, and 11, and dosing frequency set forth in the claims.

McCarthy teaches that standard treatment for pre-eclampsia consists of antihypertensive drugs (column 2 lines 9-15).

AHFS88 teaches that for the management of edema metolazone can be administered 5-10mg once a day. This amount range encompasses Applicant's

dosages set forth in claims 1, 7 and 11. AHFS88 teaches that metolazone has been administered every other day after the response of the patient was stabilized. AHFS88 teaches that Microx® (metolazone) is recommended initial adult dosage for mild to moderate hypertension is 0.5mg once daily, usually in the morning and may increase to 1mg once a day (under dosage and administration page1445).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ metolazone for the treatment of pre-eclampsia within the therapeutic dosages taught by AHFS88 because Raghunathan teaches that metolazone is an antihypertensive agent that is a standard treatment of pre-eclampsia in view of McCarthy and because AHFS88 teaches the therapeutic dosage range of metolazone for the treatment of hypertension as well as edema. One would have been motivated to make such a modification in order to achieve an expected benefit of metolazone having antihypertensive effect that is useful in the treatment of pre-eclampsia. There is a reasonable expectation of successfully treating pre-eclampsia with metolazone with the therapeutic dosages disclosed by AHFS88 because antihypertensive such as metolazone is a standard treatment that is used in the treatment of pre-eclampsia in view of McCarthy.

The amounts of active agents to be used, the dosing frequency (e.g., repeating treatment periodically or every 24 hours are taught by AHFS88), pharmaceutical formulations, mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

Further, the mechanism of action of treatment without adversely affecting the fetus and treatment without substantial volume reduction in intravascular extracellular fluid is obviously an unavoidable effect upon the administration of the same active agent with over lapping dosages in the treatment of pre-eclampsia.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicant's arguments filed July 5, 2011 have been fully considered but they are not persuasive. Applicant essentially argues that the Applicant's claimed dosages are less than a diuretic dose of metolazone. This is not persuasive because the dosages recited in claims 1, 7 and 11 are the dosages that are well known for the treatment of edema and hypertension in view of AHFS88. AHFS88 teaches that metolazone in the amount 5-10mg is the effective amount for exhibting antihypertensive effect as well as antidiuretic effect for the treatment of edema. Moreover, AHFS88 teaches lower dosage of 0.5mg can be employed to achieve antihypertensive effect. Applicant argues that considering the combination of Raghunathan and McCarthy, they are directed towa5rds different problems cannot be combined without significant destruction of the individual teaching. This is not persuasive because it is clearly known in the art in view of McCarthy that the antihypertensive drugs are the standard treatment for pre-

eclampsia while Raghunathan and AHFS88 teaches that metolazone is an antihypertensive agent. It would have been *prima facie* obvious to employ metolazone as antihypertensive for the treatment of pre-eclampsia as a standard regimen.

It is suggested that Applicants submit a declaration to clearly establish a surprising and unexpected result using Applicants teaching.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
August 1, 2011